IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA RESEARCH & DEVELOPMENT, S.N.C.,	§	
Plaintiffs,	§	
v.	§	**CIVIL ACTION NO. 3:16-cv-02207-K**
TARO PHARMACEUTICALS U.S.A., INC., TARO PHARMACEUTICAL INDUSTRIES LTD., and TARO PHARMACEUTICALS INC.,	§	
Defendants.	§	

JOINT REPORT REGARDING CONTENTS OF SCHEDULING ORDER

In accordance with the Court's Order dated October 28, 2016 [Doc. 28] (the "Order"), the parties submit this Joint Report Regarding Contents of Scheduling Order ("Joint Report"), as follows:

I. Scheduling Conference

The parties have conferred by telephone on more than one occasion to reach agreement on a case management plan. Michael C. Wilson, Jamil N. Alibhai, and Stuart E. Pollack participated on behalf of Plaintiffs Galderma Laboratories, L.P., Galderma S.A., and Galderma Research & Development, S.N.C. ("Galderma" or "Plaintiffs"). Huiya Wu, Tyler Doh, Clyde Siebman, Elvin Smith, and Stephanie Barnes participated on behalf of Defendants Taro Pharmaceuticals U.S.A., Inc. ("Taro USA"), Taro Pharmaceuticals Industries Ltd. ("Taro Israel"), and Taro Pharmaceuticals Inc. ("Taro Canada") (collectively, "Taro" or "Defendants"). The parties' positions regarding the items identified in the Court's Order [Doc. 28] are set forth

below. For the convenience of the Court, attached as **Exhibit A** is a table containing the parties' proposals for all of the deadlines discussed in this Joint Report.

II. Joint Report

1. A brief description of the nature of the case and contentions of the parties, including an explanation of the process or method covered by the patent(s) in-suit and the technology involved;

Plaintiffs' Statement:

This is a patent infringement action brought under the Hatch-Waxman Act. Galderma asserts infringement of U.S. Patent Nos. 8,445,543 (the "'543 Patent"), 8,785,420 (the "'420 Patent"), and 8,809,305 (the "'305 Patent"), collectively "the patents-in-suit." Generally, the patents-in-suit relate to methods and regimens for treatment of acne using certain combinations of adapalene and benzoyl peroxide. The patents-in-suit are listed in the FDA publication entitled, "Approved Drug Products With Therapeutic Equivalence Evaluations" (known as the "Orange Book") as covering Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3% / 2.5% ("Epiduo® Forte Gel"). This Court previously presided over a related case involving another company's filing of an Abbreviated New Drug Application ("ANDA") to market a generic version of Epiduo® Gel (adapalene and benzoyl peroxide gel, 0.1% / 2.5%).[1] In the *Actavis* matter, the Court: (i) issued a claim construction order construing terms in the '543 Patent;[2] (ii) appointed, and consulted with, a technical advisor on various issues;[3] and (iii) considered and

[1] *See Actavis*, No. 3:12-cv-02038-K (N.D. Tex.) at [Doc. 1], June 26, 2012, Compl. (the "Actavis matter").

[2] *See Actavis*, No. 3:12-cv-02038-K (N.D. Tex.) at [Doc. 163] Apr. 17, 2014, *Markman* Order.

[3] *See Actavis*, No. 3:12-cv-02038-K (N.D. Tex.) at [Doc. 111] Oct. 2, 2013, Appointment Order.

ruled on the parties' motions for summary judgment regarding validity of the patents asserted.[4] The *Actavis* matter settled in 2015. Based on this Court's familiarity with the asserted patents, on August 17, 2016, Judge Godbey transferred this matter to this Court.[5]

Plaintiff Galderma Laboratories, L.P. ("Galderma L.P."), based in Fort Worth, Texas, is a market leader in innovative dermatological products for the treatment of various skin disorders. Galderma L.P. is the exclusive beneficial holder of rights to market Epiduo® Forte Gel under FDA approval of New Drug Application ("NDA") No. 207917, approved July 15, 2015, and is owner of this NDA. Galderma L.P. has an exclusive license from Galderma S.A. and Galderma Research & Development, S.N.C. ("Galderma R&D") to sell and offer to sell Epiduo® Forte Gel in the United States. Epiduo® Forte Gel is a topical ointment prescription drug that combines a retinoid (adapalene) and an antimicrobial (benzoyl peroxide) for the treatment of acne vulgaris (including severe acne).

Prior to June 17, 2016, Taro submitted Abbreviated New Drug Application No. 209148 (the "ANDA") seeking approval to engage in the commercial manufacture, use, and sale of generic Adapalene and Benzoyl Peroxide Gel, 0.3% / 2.5% (the "Accused Product") prior to the expiration of the patents-in-suit. On or about June 17, 2016, Taro sent a letter (the "Certification Letter") to Galderma L.P. in Fort Worth, Texas and to Galderma R&D and Galderma S.A. Through the Certification Letter, Taro first notified Plaintiffs that Taro had filed the ANDA with the FDA relating to the Accused Product, and that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Taro's opinion, the claims

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[4] *See Actavis*, No. 3:12-cv-02038-K (N.D. Tex.) at [Doc. 227] Sept. 23, 2014, Order Denying Mots. for Partial Summ. J.

[5] *See* [Doc. 9].

of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of the Accused Product.

Pursuant to 35 U.S.C. § 271(e), Galderma seeks declaratory relief that Taro has and will infringe the patents-in-suit by filing the ANDA and by making or selling its Accused Product. Galderma also seeks an order that the effective date of any FDA approval of the ANDA shall not be earlier than the expiration of the patents-in-suit, as well as other injunctive relief.

Defendants have filed a motion to dismiss and/or alternatively transfer (Doc. 23). Plaintiffs will file their response to such motion on or before November 30, 2016. Defendants motion should be denied because (i) all plaintiffs have proper standing as owners or exclusive licensees of the patents, (ii) venue is proper under controlling law because Defendants' distribution of the Accused Product will cause infringement in this district, and (iii) Defendants' transfer analysis disregards Galderma Laboratories, L.P.'s substantial ties to this district, the substantial evidence present in this district, numerous relevant witnesses residing in this district and this Court's prior familiarity with the patents-in-suit.

Defendants' Statement:

This case is about Taro's desire to sell a generic version of Epiduo® Forte Gel ("Taro's ANDA Product"), which is used for the treatment of acne vulgaris. The active ingredients in Epiduo® Forte Gel are adapalene and benzoyl peroxide: these are old active ingredients and their combination has long been known and used to acne. The patents in suit here are directed to certain methods of using a topical composition containing 0.1% to 0.3% adapalene and 2.5% benzoyl peroxide.

On March 8, 2016, Taro USA filed ANDA No. 209148 ("Taro's ANDA") seeking FDA approval to market Taro's ANDA Product. Pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.949(a)(12)(i)(A)(4), Taro's ANDA included a Paragraph IV certification, stating

that the patents-in-suit are invalid, unenforceable and/or not infringed by Taro's ANDA Product. On June 17, 2016, Taro sent a letter ("Notice Letter") to Galderma notifying it that Taro had submitted Taro's ANDA to the FDA, which included a Paragraph IV certification stating that the patents-in-suit are invalid, unenforceable and/or not infringed by Taro's ANDA Product.

The filing of Taro's ANDA with a Paragraph IV certification triggered this action: on July 29, 2016, Galderma brought suit against Taro in this Court, asserting infringement of the patents-in-suit.

On October 27, 2016, Defendants filed an Answer (Doc. 26), among other things bringing affirmative defenses and counterclaims that the patents-in-suit are invalid, unenforceable and/or not infringed by the Defendants. Defendants also have filed a motion to dismiss and/or alternatively transfer (Doc. 23), seeking to dismiss the Complaint filed by Galderma L.P. and Galderma S.A. for the reason that each of these parties lack standing as co-Plaintiffs. Plaintiffs allege that Galderma L.P. and Galderma S.A. have "exclusive" rights to sell and market certain products, but fall short of alleging that either entity has any exclusive rights *in the asserted patents*, which are purportedly owned by Galderma R&D. Without an exclusive patent license, Galderma L.P. and Galderma S.A. lack standing to sue for infringement.

Defendants also filed a motion to dismiss and/or alternatively transfer (Doc. 23), seeking to dismiss the Complaint as to all Plaintiffs for the reason that venue is improper in the Northern District of Texas, Dallas Division and in the alternative a motion to transfer venue to the Southern District of New York for the convenience of the parties and witnesses and in the interest of justice.

Taro respectfully requested that: (1) all claims against Taro be dismissed with prejudice, that all relief requested by Plaintiffs be denied, and that Plaintiffs take nothing by their Complaint; (2) a judgment be entered declaring that Taro USA has not and does not infringe

directly, indirectly, literally, or under the doctrine of equivalents, any valid and enforceable claim of the patents-in-suit; that Taro USA has a lawful right to obtain FDA approval of Taro's ANDA and manufacture, import, use, sell, and/or offer to sell Taro's ANDA Product once approved by the FDA; (3) a judgment be entered declaring that the claims of the patents-in-suit are invalid for failing to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103, and/or 112, or other judicially created bases for invalidity; (4) a preliminary and permanent injunction be issued enjoining Galderma, its parents, and/or subsidiaries, and its agents, representatives, attorneys, and those person in active concert, or participation with it who receives actual notice thereof from threatening or initiating infringement litigation against Taro or any of its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Taro, or charging them either orally or in writing, with infringement of the patents-in-suit; (5) a judgment be entered declaring that this action is an exceptional case within the meaning of 35 U.S.C. § 285, declaring that Taro is entitled to recover its reasonable attorneys' fees upon prevailing in this action, and awarding Taro costs, attorney's fees, and other relief, both legal and equitable, to which it may be justly entitled.

2. A proposed time limit to file motions for leave to join other parties;

The parties propose the following deadlines:

Event	Proposed Deadline
Last day to file motion for leave to join other parties	01/31/17

3. A proposed time limit to amend the pleadings;

The parties propose the following deadlines:

Event	Proposed Deadline
Last day to amend pleadings	02/17/17

4. A proposed time limit to file various types of motions, including dispositive motions. The Court prefers the deadline for dispositive motions to be 120 days before trial and cannot be less than 90 days before trial;

The parties propose the following deadlines:

Event	Proposed Deadline
Last day to file dispositive motions	5/4/18

5. A proposed time limit for initial designation of experts;

The parties propose the following deadlines:

Event	Proposed Deadline
Opening expert reports regarding issues for which a party has burden of proof	1/16/18

6. A proposed time limit for responsive designation of experts;

The parties propose the following deadlines:

Event	Proposed Deadline
Responsive Expert Reports (including Plaintiffs' Expert report re Secondary Considerations of Nonobviousness)	2/28/18
Defendant's Expert Report responding to Secondary Considerations of Nonobviousness	3/20/18

7. A proposed time limit for objections to experts (i.e., *Daubert* and similar motions);

The parties propose the following deadlines:

Event	Proposed Deadline
Last day to file *Daubert* motions	5/11/18

8. A proposed plan and schedule for discovery, a statement of the subjects on which discovery may be needed, a time limit to complete factual discovery and expert discovery, and a statement of whether discovery should be conducted in phases or limited to or focused upon particular issues;

The parties propose the following schedule for the phases of discovery:

Event	Proposed Deadline
Last day to serve initial disclosures under Fed. R. Civ. P. 26(a)	12/14/16
Fact discovery deadline	12/15/17
Expert discovery deadline	4/20/18

The parties propose that the above discovery deadlines may be amended by agreement of the parties, provided that the amendment does not affect the trial date, and/or motion deadlines set forth in the Court's Scheduling Order.

Anticipated Discovery - Plaintiffs:

Plaintiffs anticipate that discovery may be needed with respect to the following subjects:

- The ANDA, including all amendments, supplements, related correspondence and batch samples;
- Defendants' proposed gel product, including documents and information related to the conception, reduction to practice, creation, design, development, formulation, testing, manufacturing, labeling, engineering, distribution, sale and/or modification of the product described in the ANDA;
- Defendants' evaluation and assessment of Epiduo® Forte Gel and/or the patents-in-suit, including as to willful infringement;
- Defendants' infringement of the patents-in-suit and the need for injunctive relief;
- Defendants' theories regarding alleged invalidity of the patents-in-suit, including the scope and content of alleged prior art relied on by Defendants;
- Defendants' expected or actual sale or marketing of its the proposed gel, and/or the commercial success of Epiduo® Forte Gel; and
- Secondary considerations regarding non-obviousness of the patents-in-suit and/or Epiduo® Forte Gel.

Plaintiffs identify the above topics without in any way limiting their right to seek any and all relevant discovery.

Anticipated Discovery – Defendants:

Defendants anticipate that discovery may be needed with respect to the following subjects:

- Documents and things relating to U.S. and foreign regulatory applications and approvals for adapalene and benzoyl peroxide gel, including, but not limited to, NDA 207917 for Epiduo® Forte Gel;
- Documents and things relating to the prosecution of the applications that issued as the patents-in-suit, and any foreign counterparts or priority applications to the patents-in-suit;
- Documents and things relating to ownership and license agreements for the patents-in-suit;
- Plaintiffs' Epiduo® Forte gel product, including documents and things related to the conception, reduction to practice, creation, design, research, development, formulation, testing, manufacturing, labeling, engineering, clinical trials, distribution, sale and/or modification of the product described in NDA 207917;
- Plaintiffs' Epiduo® gel product, including documents and things related to the conception, reduction to practice, creation, design, research, development, formulation, testing, manufacturing, labeling, engineering, clinical trials, distribution, marketing, sale and/or modification of the Epiduo® gel product;
- Plaintiffs' evaluation and assessment of Defendants' ANDA product and/or the patents-in-suit;
- Plaintiffs' theories regarding alleged infringement of the patents-in-suit, including the documents relied on by Plaintiffs;
- Plaintiffs' theories regarding invalidity of the claims of the patents-in-suit, including the documents relied on by Plaintiffs;
- Plaintiffs' decision to file, or not file, terminal disclaimers for the patents-in-suit, including the documents relied on by Plaintiffs;
- Plaintiffs' expected or actual sale or marketing of Epiduo® Forte Gel, and/or the commercial success of Epiduo® Forte Gel; and
- Secondary considerations relating to Epiduo® Forte Gel that allegedly rebut the *prima facie* case of obviousness of the patents-in-suit.

Defendants identify the above topics without in any way limiting their right to seek any and all relevant discovery.

9. What changes should be made in the limitations on discovery imposed under the Federal Rules of Civil Procedure or by local rule, and what other limitations should be imposed;

The parties propose the following changes (underlined) to paragraph 8 of the protective order:

> 8. Subject to paragraph 9 below, Confidential Attorney Eyes Only Information may be disclosed by the receiving party only to the following individuals, provided that such individuals are informed of the terms of this Protective Order: (a) outside counsel for the receiving party; (b) supporting personnel employed by outside counsel, such as paralegals, legal secretaries, data entry clerks, legal clerks, private photocopying services; (c) experts or consultants; and (d) those individuals designated in paragraph 11(c). Under no circumstances will the receiving party disclose Confidential Attorney Eyes Only Information to individuals who are involved, either formally or informally, in patent prosecution (including, without limitation, participation or consultation in prosecution of future or pending patent application, reexaminations, reissues, or post-grant review proceedings), or any Food and Drug Administration ("FDA") counseling, litigation, regulatory approval, citizens petition, or other work before or involving the FDA relating to the drug product(s) described in NDA 207917 or ANDA 209148.

10. A proposed trial date, estimated number of days required for trial, and whether a jury has been properly demanded; (The parties should note that the Court operates a three-week docket beginning the first Monday of each month. Therefore, the parties should propose a trial date which corresponds with the first Monday of the agreed month.)

The parties' proposals for a trial date and pretrial filings are as follows:

Event	Proposed Deadline
Last day to file pretrial disclosures (witnesses, deposition designations, and exhibits each party intends to use at trial)	6/28/18
Last day to object to pretrial disclosures	7/19/18
Last day to file Joint Pretrial Order	8/8/18
Pretrial Conference	8/30/18
Trial	9/4/18

At this time, the parties estimate the trial to last up to 5 days. Because the parties currently do not seek money damages, the case will be tried to the Court. In the event Defendants commercially manufacture, use, sell, offer to sell, or import the product described in the ANDA, Plaintiffs properly made a jury demand with the Complaint in this action [Doc. 1].

The Hatch-Waxman Act provides for a 30-month stay of Food and Drug Administration approval of the ANDA for a proposed generic pharmaceutical product. *See* 21 U.S.C. § 355(j).

Pursuant to 21 U.S.C. § 355(j)(5)(B(iii), the FDA's approval of the ANDA is stayed for a period of 30 months from Taro's service of the Certification Letter, or until December 17, 2018. The parties request the above trial date to provide the Court with a reasonable time following trial to issue a decision. The parties intend on submitting a Joint Pretrial Order that includes an expedited post-trial briefing schedule including: opening briefs due within 14 days from the end of trial, response briefs due within 14 days after opening briefs.

11. A proposed date for further settlement negotiations;

The parties cannot accurately assess the prospects for settlement at this time. The parties' proposed mediation deadline is as follows:

Event	Proposed Deadline
Mediation Deadline	2/28/18

12. Objections to Fed. R. Civ. P. 26(a)(1) asserted at the Scheduling Conference, and other proposed modifications to the timing, form, or requirements for disclosure under Rule 26(a), including a statement as to when disclosures under Rule 26(a)(1) were made or will be made;

The parties make no objections to the requirements set forth in Fed. R. Civ. P. 26(a)(1), and request no modifications to the same. The parties propose to make their Rule 26(a)(1) disclosures according to the following deadlines:

Event	Proposed Deadline
Last day to serve initial disclosures under Fed. R. Civ. P. 26(a)	12/14/16

13. Whether the parties will consent to trial (jury or non-jury) before U.S. Magistrate Judge);

The parties do not consent to trial before a U.S. Magistrate Judge.

14. Whether the parties are considering mediation or arbitration to resolve this litigation and a statement of when alternative dispute resolution would be most effective (*e.g.,* before discovery, after limited discovery, after motions are filed, etc.), and, if mediation is proposed, the name of any mediator the parties jointly recommend to mediate the case;

The parties anticipate conducting mediation after the parties are in a better position to accurately assess the prospects for settlement, and believe mediation will be the most effective ADR process. The parties have agreed to mediate with Hon. Jeff Kaplan. The parties' proposed mediation deadline is as follows:

Event	Proposed Deadline
Mediation Deadline	2/28/18

15. Any other proposals regarding scheduling and discovery that the parties believe will facilitate expeditious and orderly preparation for trial;

The parties intend to utilize the Protective Order set forth in Appendix A to N.D. Tex. Misc. Order No. 62, with the proposed modification set forth in Section 9. The parties shall serve a privilege log pursuant to Rule 26(b)(5) at a mutually agreed time. The parties anticipate they will reach an agreement regarding which categories of documents need to be included in such privilege logs.

16. Whether a conference with the Court is desired and the reasons for requesting a conference; and

At this time, the parties do not request a scheduling conference.

17. Any other matters relevant to the status and disposition of this case, including any other orders that should be entered by the Court under Fed. R. Civ. P. 16(b), 16(c), and 26(c).

At this time, the parties do not identify any other matters relevant to the status and disposition of this case other than the parties' proposed modifications to paragraph 8 of the

protective order (Appendix A to NDTX Amended Misc. Order No. 62) noted herein in paragraph 9 above.

18. Proposed modifications of the presumptive deadlines established by N.D. Tex. Misc. Order No. 62.

The parties' proposals regarding the presumptive deadlines set forth in Misc. Order 62 are as follows:

Event	Proposed Deadline
Last day to serve Infringement Contentions under N.D. Tex. Misc. Order No. 62 ¶ 3-1 and document production under ¶ 3-2	1/10/17
Last day to serve Invalidity Contentions under N.D. Tex. Misc. Order No. 62 ¶ 3-3 and document production under ¶ 3-4	02/28/17
Last day to exchange proposed terms and claim elements for claim construction under N.D. Tex. Misc. Order No. 62 ¶ 4-1	03/14/17
Last day to exchange preliminary claim constructions and related extrinsic evidence under N.D. Tex. Misc. Order No. 62 ¶ 4-2	04/14/17
Last day to file Joint Claim Construction Statement	04/28/17
Claim construction-related discovery deadline	4/26/17
Last day to file Claim Construction Opening Briefs; and expert reports in support thereof (if necessary)	6/5/17
Last day to file Claim Construction Responsive Briefs; and expert rebuttal reports	6/21/17

The parties propose that the above claim-construction deadlines may be amended by agreement of the parties, provided that the amendment does not affect the *Markman* briefing and/or hearing (if any) date(s) set in this matter.

a. Whether an evidentiary *Markman* hearing or oral argument on claim construction issues is desired;

The parties request oral argument regarding claim construction issues. The parties do not currently anticipate the need for live witness testimony regarding claim construction. However, the parties reserve the right to call live witnesses, and will provide advance notice of their desire to do so no later than the filing of the parties' Joint Claim Construction Prehearing Statement pursuant to Misc. Order 62 ¶ 4-3.

b. Whether a special master or technical expert should be appointed to assist the court in determining claim construction and patent-related issues; and

At this time, the parties believe a special master or technical advisor would assist the Court in determining patent-related issues. In the *Actavis* matter, the Court appointed Daniel Denton as special master.[6]

c. Whether any party believes that a technical tutorial would be helpful and, if so, a proposal for presenting such a tutorial to the presiding judge.

At this time, the parties do not believe a technical tutorial separate and apart from the *Markman* hearing is necessary. However, should the Court desire one, the parties are willing to present a technical tutorial either through submission of separate tutorials to the Court before the date of the *Markman* hearing, if any, or at the *Markman* hearing itself.

[6] *See Actavis*, No. 3:12-cv-02038-K (N.D. Tex.) at [Doc. 111] Oct. 2, 2013, Appointment Order.

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2016, all counsel of record who are deemed to have consented to electronic service are being served with a copy of this instrument via the Court's CM/ECF filing.

/s/ Michael C. Wilson
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